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Randomized controlled trial examining the adjunctive use of nicotine lozenges with MyLastDip: An eHealth smokeless tobacco cessation intervention

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ABSTRACT

Introduction: Promising Web-based interventions for smokeless tobacco cessation have emerged. We describe a randomized controlled trial (RCT) testing the relative benefits of adding the nicotine lozenge as an adjunct to the MyLastDip Web-based smokeless tobacco cessation intervention.
Methods: 407 smokeless tobacco users who wanted to quit were recruited, screened online, and randomly assigned to one of two conditions: (a) the interactive MyLastDip Web-based intervention (Web Only; $n = 202$), or (b) the website plus the offer of nicotine lozenges (Web + Lozenge; $n = 205$). MyLastDip program content is grouped according to three sequential *frames*: preparing to quit, quitting, and staying quit. If a participant reported a lapse then the program would provide tailored content on lessons learned and starting over ("retooling"). The primary outcome was 7-day point prevalence tobacco abstinence measured at follow-up assessments that occurred 3 months and 6 months post-enrollment.
Results: Assessment completion rates were 71.5% at 3 months, 72.9% at 6 months, and 65.1% for both 3 and 6 months, and did not differ by condition. Using Intent to Treat analyses, the Web + Lozenge condition was associated with a significantly higher 7-day point prevalence tobacco abstinence rate than the Web Only condition at 3 months (43.4% vs. 29.7%, $p = .004$), at the combined 3 and 6 month assessment of repeated point prevalence (35.6% vs. 23.3%, $p = .007$), but not at 6 months (44.4% vs. 35.1%, $p = .057$). Similar results were obtained for smokeless tobacco abstinence. Participants reported being satisfied with their programs and the Web + Lozenge condition participants visited the *MyLastDip* program more often ($p < .001$). A composite engagement measure of the number and duration of program visits was positively related to 6-month tobacco abstinence ($p = .009$).
Conclusions: Consistent with previous research, the MyLastDip Web-based tobacco cessation intervention encouraged long-term levels of tobacco and smokeless tobacco abstinence. The addition of nicotine lozenges significantly improved both participant engagement and self-reported 7-day point prevalence tobacco abstinence at 3 months and when considering 3- and 6-month repeated point prevalence tobacco abstinence.

1. Background

Smokeless tobacco includes use of either chewing tobacco (user chews tobacco typically packaged in foil pouches); moist snuff (finely ground tobacco not chewed but placed between the cheek and gums and packaged in tins or cans); and snus, moist snuff processed to reduce cancer-causing nitrosamines, marketed in small tea bags packaged in tins. Smokeless tobacco does not include electronic or e-cigarettes or waterpipes.

Smokeless tobacco is a serious public health problem in the U.S. (USDHHS, 2012) and it is used by almost 8 million American adults (7.1% of men and 0.4% of women) (SAMHSA, 2013). Although using smokeless tobacco is less harmful than smoking cigarettes (Lee and Hamling, 2009), both the U.S. Department of Health and Human Services (U. S. National Toxicology Program, 2014) and the World Health Organization (International Agency for Research on Cancer, 2012) have concluded that it contains known human carcinogens. For example, studies indicate that smokeless tobacco is a cause of cancer of the throat, stomach (Mattson and Winn, 1989), and pancreas (Alguacil and Silverman, 2004).

Our research group has developed and evaluated eHealth smokeless tobacco cessation interventions — the ChewFree program (Severson

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et al., 2008) and the more recent MyLastDip program (Danaher et al., 2013). Both are fully automated Web-based interventions designed to be used on personal computers, and incorporate tailored content, graphics, interactive activities, practice audios, and testimonial videos, and have used Web forums. Both programs have displayed highly encouraging results in terms of all-tobacco abstinence.

Another thrust in smokeless tobacco cessation research has examined the use of nicotine lozenges. Nicotine lozenges are part of the larger family of nicotine replacement therapy (NRT) products which have been found to increase smoking cessation treatment efficacy by 50% to 70% (Stead et al., 2012) but they have shown equivocal benefits as adjuncts to smokeless tobacco cessation (Ebbert et al., 2011). Over a number of studies (Ebbert et al., 2007; Ebbert et al., 2010a; Ebbert et al., 2009, 2010b, 2013; Severson et al., in press), our team has examined the effects and acceptability of following a regimen of using nicotine lozenges by smokeless tobacco users who want to quit. In one study (Ebbert et al., 2013) we found that using nicotine lozenges attenuated the experience of withdrawal symptoms, and this was related to greater short-term tobacco abstinence. In a more recent smokeless tobacco cessation trial (Severson et al., in press), we examined the extent to which lozenges benefited from the support provided in telephonic coach calls. Results showed that combining nicotine lozenges and phone counseling significantly increased tobacco abstinence rates compared to either intervention alone (Severson et al., in press).

This present study was informed by both of the previously described research threads — Internet intervention and nicotine lozenges. Smokeless tobacco users who sought help to quit via an Internet program were randomized to the Web condition or the Web plus the offer of free lozenges. Our hypothesis was that participants assigned to the Web + Lozenge condition would have significantly increased abstinence of all-tobacco and smokeless tobacco abstinence compared to the Web Only condition.

2. Methods

2.1. Participants

Participant recruitment for the current study occurred from January, 2013 to July, 2013. We used a nationwide Google AdWords online marketing campaign to recruit an average of 15 study participants each week until 407 study participants were enrolled. The campaign (both in online listings and content on the study marketing page) described a study that would compare the use of an online individualized (tailored) smokeless tobacco cessation program both with – and without – the use of nicotine lozenges. Individuals who indicated interest in participating pressed a button on the MyLastDip.com project marketing website to initiate the online screening procedure.

Interested individuals followed an online enrollment protocol having seven sequential steps: (1) registration, (2) screening, (3) informed consent, (4) sharing contact information, (5) baseline assessment, (6) randomization to condition, and (7) an email invitation to visit the website and offer of lozenges. The time required to complete this protocol was approximately 10–15 min.

An automated registration procedure was triggered when respondents pressed a "sign up" button on the project marketing website, which asked them to submit their email address. Respondent requests with email addresses not already in our database of the current study and our other ongoing studies were then sent an email invitation with login information to start the online screening process. In order to be eligible for possible inclusion, respondents submitting screening data indicated that they were: (1) at least 18 years old, (2) used smokeless tobacco on a daily basis for at least 1 year; (3) agreed to quit using tobacco within the next month, (4) a U.S. resident, and (5) could read English. Respondents were excluded if they endorsed any of the following: (1) used other behavioral or pharmacologic tobacco treatment programs for tobacco cessation or reduction during the previous 30 days; (2) had another household member participating in the study; or (3) reported any of a series of medical/health conditions that were precautions related to our use of nicotine lozenge: unstable angina, myocardial infarction within the previous 6 months, cardiac dysrhythmia other than medication-controlled atrial fibrillation or paroxysmal supraventricular tachycardia (PSVT), hypertension with blood pressure of $\geq$180 systolic or $\geq$100 diastolic, phenylketonuria (PKU); or currently pregnant or nursing. Individuals were also excluded whose mailing address matched one already recorded in our database of prior respondents. Individuals deemed ineligible as well as those not interested in participating were offered free access to the MyLastDip cessation program (Danaher et al., 2013), which was made freely available in a non-research mode (without assessments).

The study protocol was approved by Oregon Research Institute's (ORI) Human Subjects Institutional Review Board (approval # FWA00005934).

2.2. Study design

A randomization sequence vector was used to randomly assign eligible individuals to one of the two experimental conditions:

(1) MyLastDip only (Web Only; $n = 202$)
MyLastDip program is an engaging and interactive Web-based intervention. Program content is grouped according to three sequential *frames*: preparing to quit, quitting, and staying quit. If a participant reported a lapse then the program would provide tailored content on lessons learned and starting over ("retooling"). The program incorporated activities designed to encourage participant engagement, including the creation of a personal quitting plan. Participants were able to create personal lists (e.g., reasons for quitting), calculate how much money they would save once quit, watch videos of smokeless tobacco quitters who successfully overcame challenges to quit, listen to relaxation audios and videos, choose a quit date and method, and create a personal quitting contract (Figs. 1 and 2). The program also included a Resource section that described the ingredients of smokeless tobacco, the role of nicotine, health effects of using smokeless tobacco, prescription medications, types of nicotine replacement therapies (NRT), fake chew or herbal snuff, and links to websites that contained additional information.
Automated email reminders were sent to participants in order to encourage their use of the program. For example, if a participant did not indicate a quit date, then they were sent a reminder email to encourage them to visit the website in order to choose a quit date and benefit from other useful strategies. Supportive emails were also sent 2 days, 1 week, and 2 weeks after their quit dates. Some of the email content provided a general endorsement of the use of NRT products. Emails were also sent to prompt completion of scheduled follow-up assessments. Additional details regarding the MyLastDip program can be found in our prior report (Danaher et al., 2013). The version of the program used for the current trial was updated so that it was appropriate for use by older adults rather than the study population of 14–25 year olds in the original study.

(2) MyLastDip plus Lozenges (Web + Lozenge; $n = 205$)
In addition to being invited to use the MyLastDip program, participants assigned to the Web + Lozenge condition were mailed 2 boxes of Nicorette® Lozenges (4 mg; 108 lozenges per box). Written instructions were provided describing the tapering schedule to use for taking lozenges: weeks 1 to 6 (1 lozenge every 1–2 h), weeks 7 to 9 (1 lozenge every 2–4 h), and weeks 10 to 12 (1 lozenge every 4–8 h). During the first

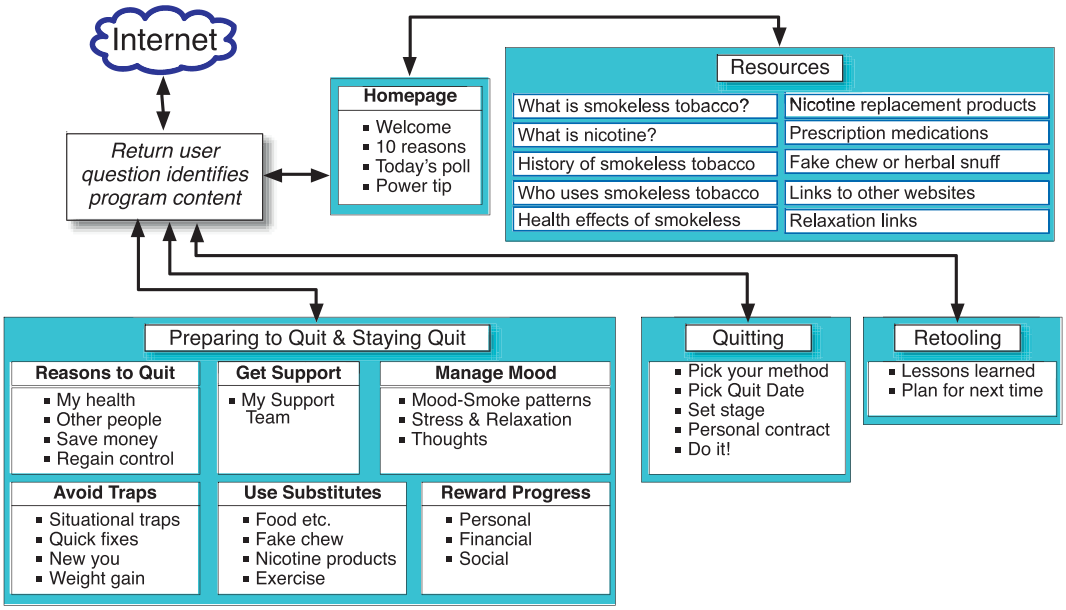

Fig. 1. *MyLastDip* program features.

3 months post enrollment participants could call the research project toll-free phone line in order to obtain up to a maximum of 12 additional free boxes of lozenges in units of 2 boxes per request. In addition to the pattern of emails noted earlier for the Web Only condition, participants in this condition received emails that reinforced the rationale for using lozenges ("Remember, using the lozenges regularly helps you control cravings before they occur.") and provided usage instructions tailored to the timing of the tapering schedule.

2.3. Assessment plan and measures

All participants completed a baseline assessment and were asked to complete follow-up assessments scheduled to occur 3 and 6 months following enrollment. All assessments were available online although research staff called participants if assessments were not completed within 2 weeks of their scheduled date. Participants received $15 for completing each follow-up assessment and an additional $25 for completing both assessments.

The baseline assessment measured socio-demographics (age, gender, race/ethnicity, marital status, educational background), smokeless tobacco usage variables (years of use, number of quit attempts (*…serious attempt to quit using smokeless tobacco more than 24 h in the last 12 months*), amount of use, friends' use), tobacco dependence, readiness to quit, depression status, alcohol consumption, and anticipated partner support for quitting.

Partner support was assessed by asking "How supportive do you expect your partner to be of your effort to quit tobacco?" which they rated using 1 = *Not at all supportive*, 2 = *Somewhat supportive*, 3 = *Supportive*, and 4 = *Very supportive*. Dependence was assessed two ways. First, we used the Severson Smokeless Tobacco Dependence Scale (Ebbert et al., 2012) that has scores ranging from 0 to 19 (larger values indicating higher dependence). Secondly, dependence was also measured using a single item, asking if the first morning use occurs within 30 min of waking. This measure has been found to be a predictor in our prior research and has been singled out for its predictive power for smoking cessation (Baker et al., 2007).

Readiness to quit was assessed using the contemplation ladder (Biener and Abrams, 1991) adapted for smokeless tobacco cessation using an 11-point Likert scale with 1 = *Not ready to quit*, 3 = *Should consider quitting someday*, 5 = *Should quit but not quite ready*, 7 = *Thinking about cutting down or quitting*, 9 = *Have cut down and seriously considering quitting*, and 11 = *Ready to quit now*. Participant self-efficacy was assessed using the item that asked "How confident are you that you will not be using any tobacco a year from now?" and used a five-point Likert scale: 1 = *Not at all confident*, 3 = *Somewhat confident*, and 5 = *Completely confident*. Participant depression status was assessed using the two-item Patient Health Questionnaire (PHQ-2; Kroenke, Spitzer, & Williams, 2003) that asked "Over the past two weeks, how often have you been bothered by any of the following problems?" using two items: "Feeling down, depressed or hopeless" and "Little interest or pleasuring in doing things?" The assessment was scored as the overall sum of the responses scored as 0 = Not at all, 1 = Several days, 2 = More than half the days, and 3 = Nearly every day. Alcohol status was assessed by asking an item used to screen problem drinking status (NIAAA, 2005): *How many times per month do you drink more than 3–4 drinks on a single occasion?*

Primary tobacco outcomes were self-reported 7-day point prevalence tobacco use measured at baseline and the 3- and 6-month follow-up assessments. These outcomes considered "all tobacco" defined as self-reported non-use of smokeless tobacco, cigarettes, cigars, and pipes. We also assessed smokeless tobacco abstinence separately. Secondary tobacco outcomes assessed reduced smokeless tobacco use (number of cans/pouch used per week), and the number of quit attempts since enrolling in the project.

Lozenge usage in the Web + Lozenge condition was assessed with the question: "*Since you received the nicotine lozenges, have you been using them* (*None of the days*, *Few days*, *Less than half of the days*, *More than half of the days*, and *Most days*)" and "*On the days that you used the lozenges, how much of each day did you use them?*" (*I didn't use lozenges*, *Little of the day*, *Less than half the day*, *More than half the day*, *Most of the day*). Requests for supplemental lozenges were recorded by project staff.

Program usability was measured at the 3-month follow-up using a 6-point scale: *Very difficult* to *Very easy*. Acceptability was measured by asking participants if they would recommend the program to friends or family members who use chew/snuff. Additional usability items

Fig. 2. *MyLastDip* screenshot.

regarding nicotine lozenge use were asked of participants in the Web + Lozenge condition.

Usage of the MyLastDip website over the entire course of the program was measured unobtrusively for all participants including the number of visits, the duration of these visits, and specific webpages visited.

2.4. Statistical analyses

SPSS (version 19) was used for all statistical analyses.

Post hoc sensitivity analyses were conducted using G*Power 3.1 (Erdfelder et al., 1996; Faul et al., 2007) to identify the detectable effect sizes for each outcome evaluated. For primary outcome measures, the sensitivity analysis was evaluated as a two-tailed test, the sample size available for each time point (3 months, 6 months, and both 3 and 6 months) and analysis type (Complete Case and ITT), statistical power set at $1 - \beta = .90$, and an adjusted significance level, also referred to as an error probability, of $\alpha = .004$ (.05/12) to accommodate the number of tests used to evaluate the all tobacco and smokeless tobacco primary outcome measures. For secondary outcome measures, the sensitivity analysis was evaluated as a two-tailed test, with the sample size available for each analysis (3 month, 6 month; Complete Case), statistical power set at $1 - \beta = .90$, and an adjusted significance level, of $\alpha = .025$ (.05/2) to accommodate the evaluation at each time point (3 month and 6 month).

Primary Tobacco Outcome Analyses assessed 7-day point prevalence abstinence for all tobacco as well as for smokeless tobacco use by including analysis of Complete Cases (participants who completed assessments) and Intent to Treat (ITT) imputation analysis (missing cases considered to be using tobacco). Results were analyzed separately for the 3- and 6-month follow-up assessments as well using a repeated point prevalence measure that combined 3- and 6-month assessments as a measure of more lasting abstinence. Secondary analyses assessed reductions in smokeless tobacco usage (number of cans, pouches, or tins used per week from baseline to follow-up) and number of quit attempts since project enrollment among participants who continued to use tobacco. *Reduced usage* was calculated as a dichotomous item derived from the amount of usage reported at baseline and follow-up,

with a value of 1 indicating a reduction of usage from baseline to follow-up and a 0 indicating the same or an increase in usage from baseline to follow-up. Secondary outcomes were assessed using ANOVA and Chi-Square analyses.

Possible predictors of tobacco outcomes were assessed using a two-step procedure. First, a univariate binary logistic regression was used to test the baseline participant characteristics as predictors of tobacco abstinence at the combined 3- and the 6-month assessments. Those predictors reaching significance on the univariate test were then included in a multivariate binary logistic regression test using backwards elimination to remove nonsignificant variables. To identify any differential effects of the intervention on the prediction of these outcomes the multivariate test included treatment condition as well as the interaction of condition with sample characteristics.

2.4.1. Program acceptability and usage

Program usage and acceptability were assessed using ANOVA, Non-parametric Mann–Whitney *U* and Chi-Square analyses. Logistic regressions were used to evaluate program usage by the measure of tobacco abstinence at the 6-month assessment. Website program engagement was measured using the composite measure defined as the mean of the *z* score transformations of visits (number) and duration (minutes) (Danaher et al., 2006).

3. Results

Of the 407 study participants, 291 (71%) completed the 3-month follow up assessment (141 or 48.5% using the online assessment and 150 or 51.5% via phone calls). The 6-month follow-up assessment was completed by 297 (73%) participants (165 or 55.6% using the online assessment and 132 or 44.4% via phone calls). A total of 265 (65%) completed both assessments. Assessment completion rates did not vary by condition or sample characteristics (see CONSORT diagram, Fig. 3).

Participant characteristics at baseline, described in Table 1, show that the sample was nearly all male and approximately 35 years of age. These findings are consistent with our prior smokeless tobacco cessation studies (e.g., Severson et al., 2008). No differences on baseline participant characteristics were found between the two conditions.

3.1. Tobacco outcomes

ITT results for 7-day point prevalence tobacco abstinence across conditions were 36.6% (149/407) at 3 months, 39.8% (162/407) at 6 months, and 29.5% (120/407) considering both 3 and 6 months. ITT results for smokeless tobacco abstinence were only slightly higher: 39.8% (160/407) at 3 months, 42.5% (173/407) at 6 months, and 34.9%, (130/407) at both 3 and 6 months.

3.1.1. Tobacco outcomes by condition

Using Cohen's (1988) guidelines, the analyses of primary and secondary outcome measures were adequately powered to detect small to medium sized effects between groups.

Table 2 describes the self-reported tobacco abstinence results (7-day point prevalence) across the two follow-up assessments as well as for repeated point prevalence (both 3- and 6-months follow-up). The top panel shows results for all tobacco and the bottom panel shows results for smokeless tobacco. Participants in the Web + Lozenge condition displayed significantly greater tobacco abstinence than those in Web Only at 3 months and at both 3 and 6 month repeated point prevalence: 3 months: OR = 1.816 [95% CI: 1.206, 2.734], $p = .004$; 6 months: OR = 1.473 [95% CI: 0.988, 2.195], $p = .057$; repeated point prevalence: OR = 1.824 [95% CI: 1.182, 2.0], $p = .007$. The results were similar for smokeless tobacco abstinence.

For participants who did not achieve repeated point abstinence, 70% (91/130) reported reductions in smokeless tobacco used between baseline and 3-month follow-up and 79% (98/124) reported reductions between baseline and 6-month follow-up. Of the participants reporting five or more cans or pouches per week, 76% (54/71) reported a reduction in use at 3 months and 81% (58/72) at 6 months. Reductions in use did not differ by condition. Continuing smokeless tobacco users reported 2.79 (SD = 1.8) quit attempts since enrolling in the project at the 3-month follow-up and 3.27 quit attempts (SD = 1.7) at the 6-month follow-up. Participants in the Web + Lozenge condition reported more quit attempts since enrolling in the project at the 3-month follow-up assessment compared to the Web Only condition (Web + Lozenge: M = 3.17, Web Only: M = 2.47; $F(1,129) = 4.81$, $p = .030$). However, the number of quit attempts between baseline and the 6-month follow-up did not differ by condition.

3.2. Predictors and moderators of tobacco outcomes

An analysis of predictors revealed that repeated point tobacco abstinence at 3 and 6 months was more likely to be reported by participants who were not current smokers ($\beta = -2.64$; $p = .012$; OR = 0.0712 [0.009,0.560]), those who have smoked less than 100 cigarettes in their lifetime ($\beta = -0.583$; $p = .027$; OR = 0.558 [0.333, 0.937]), and those with higher self-efficacy in their ability to quit ($\beta = 0.375$; $p = .0008$; OR = 1.456 [1.102,1.923]). However, when the variables were evaluated as moderators, no effects were detected.

3.3. Program acceptability and engagement

3.3.1. Participant use of the MyLastDip program

Study participants spent an average of 25.23 min viewing the website (median = 15 min, SD = 31.2 min, range = 0–232 min) and made 2.35 visits (median = 1 visit, SD = 2.6 visits, range = 0–18 visits) from baseline to the 6-month follow-up. Thirty-two of the participants (8%; 32/407) never visited the Web intervention (Web Only = 5.9%, 12/202; Web + Lozenge = 9.8%, 20/205), 43.0% (175/407) visited the program only once, and 41.2% (200/407) visited multiple times. Participants in the Web + Lozenge condition visited more times than Web Only ($Z = 3.59$, $p < .001$); there were no between-condition differences in the duration of website visits. For complete cases, the engagement composite (all program visits and their duration) was positively related to tobacco abstinence: 3-month assessment ($\beta = 0.414$; $p = .003$; OR = 1.513 [1.156, 1.981]), 6-month assessment ($\beta = 0.363$; $p = .009$; OR = 1.437 [1.095, 1.8836]), and at both 3- and 6-month assessments ($\beta = 0.364$; $p = .015$; OR = 1.439 [1.073, 1.931]).

3.3.2. Participant use of lozenges

Of the participants who were offered lozenges, 22.92% (47/205) asked to receive supplemental lozenges during the course of the program. Those who requested additional lozenges were more likely to report tobacco abstinence at 3 months, χ^2 (1, $n = 153$) = 5.18, $p = .023$, $OR = 2.45$, 95% CI [1.12, 5.37], and 6 months, χ^2 (1, $n = 154$) = 5.18, $p = .041$, $OR = 2.20$, 95% CI [1.02, 4.71]. Of the 127 of participants who reported using the nicotine lozenges at the 3 month follow-up assessment, 58.3% (74/127) reported that they had used the lozenges on a "consistent basis" operationally defined as using lozenges more than one-half of all days and more than one-half of each of those days when used. In terms of rated helpfulness of lozenges, 87.4% of these participants (111/127) reported the lozenges were *somewhat*, *very* or *extremely effective*. A few participants reported moderate or severe symptoms associated with using lozenges: 7.2% headache, 5.6% nausea, 11.3% flatulence, 6.5% hiccups, 12.9% heartburn, 7.2% sleep disturbance, 3.2% diarrhea, 18.2% reported decreasing their lozenge use because of side effects, and 8.3% reported discontinuing lozenge use as a result.

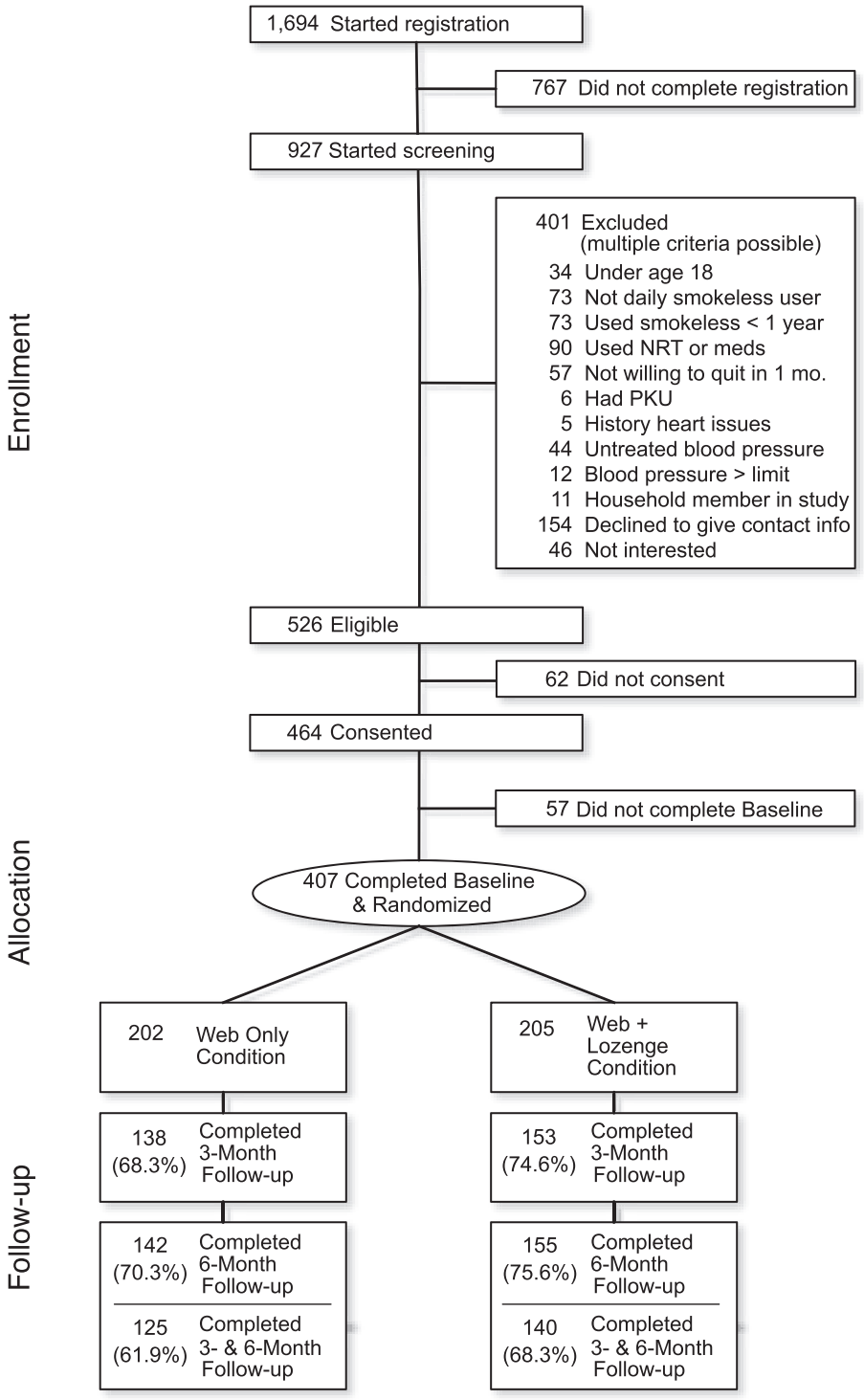

Fig. 3. CONSORT diagram.

4. Discussion

We found that including nicotine lozenges as an adjunct to an effective Web-based smokeless tobacco cessation intervention modestly but significantly improved long-term tobacco abstinence at the 3-month follow-up but only approached statistical significance at the 6-month assessment. Inspection of these data indicates that the Web + Lozenge condition maintained tobacco abstinence from 3 to 6 months (43.4% to 44.4%) whereas the Web Only condition improved over time (29.7% to 35.1%), attributable to the net increase in 11 quitters in the Web Only condition compared to a net increase of just 2 quitters in the Web + Lozenge condition.

These overall results are consistent with our previous studies that have shown that nicotine lozenges can be helpful for smokeless tobacco cessation, likely attributable to the lozenges helping to reduce the experience of withdrawal symptoms. Our findings also align well with

Table 1
Participant characteristics at baseline by condition.[a]

Characteristics	Web Only $N = 202$	Web + Lozenge $N = 205$	Total $N = 407$
Age: M (SD)	35.31 (10.4)	35.07 (10.3)	35.19 (10.3)
Male: *n* (%)	199 (98.5)	198 (96.6)	397 (97.5)
Married or have long-term partner: *n* (%)	172 (85.1)	174 (84.9)	346 (85.0)
Race/ethnicity: *n* (%)			
White	186 (94.4)	196 (95.6)	382 (95.0)
Other	11 (5.6)	9 (4.4)	20 (5.0)
Education: *n* (%)			
Not high school graduate	4 (2.0)	2 (1.0)	6 (1.5)
High school graduate	100 (49.5)	119 (58.0)	219 (53.8)
College graduate	82 (40.6)	65 (31.7)	147 (36.1)
Post graduate degree	16 (7.9)	19 (9.3)	35 (8.6)
Days can/pouch lasts: *n* (%)			
Less than one day	25 (12.4)	32 (15.6)	57 (14.0)
1 day	77 (38.1)	87 (42.4)	164 (40.3)
2 days	63 (31.2)	40 (19.5)	103 (25.3)
3 days	28 (13.9)	21 (10.2)	49 (12.0)
4 or more days	9 (4.5)	25 (12.2)	34 (8.4)
Cans/week: *n* (%)			
1–2 cans or pouches a week	27 (13.4)	41 (20.0)	68 (16.7)
3–4 cans or pouches a week	58 (28.7)	39 (19.0)	97 (23.8)
5 or more cans or pouches a week	117 (57.9)	125 (61.0)	242 (59.5)
No. years using smokeless tobacco: M (SD)	15.42 (10.5)	13.96 (9.6)	14.69 (10.1)
Tobacco dependence			
Use smokeless tobacco ≤30 min waking: *n* (%)	111 (55.0)	112 (54.6)	223 (54.8)
Tobacco dependence scale: M (SD)	11.91 (3.7)	11.28 (3.6)	11.59 (3.6)
Current smoking: *n* (%)	13 (6.4)	16 (7.8)	29 (7.1)
≥100 cigs. smoked lifetime: *n* (%)	89 (44.1)	91 (44.4)	180 (44.2)
No. quit attempts in last year: M (SD)	1.76 (1.5)	1.81 (1.7)	1.79 (1.6)
5 best friends use smokeless: M (SD)	1.91 (1.6)	1.81 (1.4)	1.86 (1.5)
Readiness to quit: M (SD)	9.82 (1.8)	9.65 (1.9)	9.73 (1.8)
Self-efficacy in not using tobacco in 1 year: M (SD)	2.48 (0.9)	2.56 (1.0)	2.52 (0.9)
Expected support from partner: *n* (%)	160 (93.0)	160 (92.0)	320 (92.5)
Depression status: M (SD)	1.36 (1.57)	1.21 (1.51)	1.54 (1.29)
How many times per month do you drink more than 3–4 drinks on a single occasion: M (SD)	3.56 (4.9)	3.76 (5.1)	3.66 (5.0)

[a] Participants were able to refuse to answer any question. Sample for all data was 407 except for expected support for which $n = 346$.

Table 2
Self-reported 7-day point prevalence tobacco abstinence at follow-up.

	3 months, *n*/*N* (%)	6 months, *n*/*N* (%)	3 and 6 months, *n*/*N* (%)
All tobacco			
Intent-to-treat analyses (ITT)			
Web Only	60/202 (29.7)**	71/202 (35.1)	47/202 (23.3)**
Web + Lozenge	89/205 (43.4)	91/205 (44.4)	73/205 (35.6)
Complete case analyses			
Web Only	60/138 (43.5)*	71/142 (50.0)	47/125 (37.6)*
Web + Lozenge	89/153 (58.2)	91/155 (58.7)	73/140 (52.1)
Smokeless tobacco			
Intent-to-treat analyses (ITT)			
Web Only	67/202 (33.2)*	79/202 (39.1)	53/202 (26.2)*
Web + Lozenge	93/205 (45.4)	94/205 (45.9)	77/205 (37.6)
Complete case analyses			
Web Only	67/137 (48.9)*	79/142 (55.6)	53/125 (42.4)*
Web + Lozenge	93/153 (60.8)	94/155 (60.6)	77/140 (55.0)

Differences between conditions at assessments and at both 3- and 6-months: *$p < .05$, **$p < .01$.

published accounts that adding nicotine lozenges to a smoking cessation program can improve abstinence outcomes (Shiffman et al., 2002; Stead et al., 2012).

It was encouraging that greater than 70% of study participants completed each individual follow-up assessment (for all 407 participants: 71.5% at 3 months; 73.0% at 6 months) and that 65.1% completed both 3- and 6-month assessments. This level of assessment completion is consistent with the follow-up completion results reported for other Web-based smokeless tobacco cessation intervention RCTs (Danaher et al., 2013; Danaher et al., 2014; Severson et al., 2008) and somewhat higher than some smoking cessation studies (e.g., Bricker et al., 2013; McKay et al., 2008; Munoz et al., 2009; Smit, de Vries and Hoving, 2012) but lower than others (e.g., Graham et al., 2011).

Engagement with the Web intervention in the current study (all participants: median number of visits and total visit duration: mean = 2.35 visits, median = 1 visit, mean = 25.23 min) was highly consistent with the results of the earlier RCT of MyLastDip (Danaher et al., 2013): mean = 2.47 visits, median = 1 visit, mean = 26.34 min. Unfortunately, many smoking cessation interventions (e.g., McClure et al., 2013; Strecher et al., 2008) have not included similar participation engagement metrics although one study (Richardson et al., 2013) reported median website visits = 2 and median total minutes duration = 32. Nonetheless, it is reasonable to assume that more participants would have benefited had they more fully engaged in their cessation program. Previous research on Web-based smokeless tobacco cessation has shown a dose–response relationship favoring tobacco abstinence (Danaher et al., 2008).

This study was not designed to separate the active ingredient and possible expectancy effects of the lozenge. However, from an applied perspective, this distinction does not matter. Our data do suggest that providing more than 2 weeks of lozenges would be beneficial. Like our prior studies on smokeless tobacco cessation, we did not validate participant self-reports with biochemical measures. This decision was informed by Glasgow et al. (1993) that biochemical validation in large low-intensity intervention trials can be impractical, negatively impact recruitment, and not likely differentially affect results by condition. While we acknowledge that our results may overestimate the actual absolute abstinence rates, we do not expect that there would be differential misreporting by study condition.

The observed abstinence levels combined with the high reach of Web-based program point to the potential public health impact and significance for these smokeless tobacco cessation interventions. They could be incorporated into stepped care tobacco cessation programs (Abrams et al., 1996) as well as an important option in established tobacco Quitline services (Abrams et al., 2010; Danaher et al., 2014; Graham et al., 2011). However, the cost of lozenges (their purchase price, shipping and handling costs) will need to be considered when deciding to use them as treatment adjuncts.

Future research possibilities could examine whether interventions like MyLastDip might be effective for snus users who want to quit (Toftgard et al., 2010). In addition, a larger effectiveness trial with an ongoing Internet smokeless tobacco cessation program would be a logical next step.

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Declaration of interests

Dr. Ebbert has received consulting fees from GlaxoSmithKline and has received research support from Pfizer, Orexigen and JHP outside of the current study.

GlaxoSmithKline provided the nicotine lozenges for the study but had no role in the conduct of the study (data collection, management, analysis, and interpretation), in the preparation, review, approval of

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